EFFICACY AND SAFETY OF NEPAFENAC 0.3% OPHTHALMIC SUSPENSION ADMINISTERED ONCE-DAILY IN PATIENTS WITH DIABETIC RETINOPATHY FOLLOWING CATARACT SURGERY

Purpose: To evaluate the efficacy and safety of once-daily nepafenac 0.3% suspension relative to vehicle based upon clinical outcomes following cataract surgery (CS) in diabetic retinopathy (DR) patients.

Method: In two identically designed, Phase 3, multicentre, double-masked, vehicle-controlled studies, patients (Study-1: 615; Study-2: 605) were randomized 1:1 to receive nepafenac or vehicle, once-daily, one day before CS, on the day of CS and for 90 days thereafter. Key endpoints included patients (%) who developed macular oedema (ME) within 90 days post-CS; patients (%) with a ?15-letter best-corrected visual acuity (BCVA) improvement from preoperative baseline to Day-14, maintained through Day-90 and safety assessments.

Results: A significantly lower proportion of patients in nepafenac group than in vehicle group developed ME within 90 days post-CS (Study-1: 2.3% vs 17.3%, p